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EXAMINER

STUART, COLIN W

ART UNIT

PAPER NUMBER

4177

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/575,866	<b>Applicant(s)</b> BELL ET AL.	
	<b>Examiner</b> COLIN STUART	<b>Art Unit</b> 4177	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 33-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to because Fig. 2 and 5 each do not have any connection between elements. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 uses the language “pressure signature” in line 5. There is insufficient explanation of a pressure signature in the specification which therefore renders the claim indefinite. The examiner is reading this language to mean a pressure signal sensed by the pressure sensor

Claim 44 uses the language “signature envelope” in line 2. There is insufficient explanation of a pressure signature in the specification which therefore renders the claim indefinite. The examiner is reading this language to mean the processed signal after filtering.

Claim 59 uses the language “temperature signature” in line 3. There is insufficient explanation of a temperature signature in the specification which therefore renders the claim indefinite. The examiner is reading this language to mean a temperature signal sensed by the pyroelectric sensor.

Claims 34-43 and 45-58 are rejected based on being dependent on the rejected claims above.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**4. Claims 33-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Rocci, Jr. et al. (6,138,669).**

In regards to claim 33, Fig. 1 of Rocci shows a metered dose inhaler dispenser having a housing (5), a pressure sensor (12), processing means (microprocessor 14; Fig. 3), a display means (LCD 15), and a dispensing container (1) being received in the housing (5). Fig. 6 of Rocci shows that the pressure sensor (12) is operatively connected to the processing means (14). Rocci's processing means is programmed to analyze the signals and compare the signals against one or more data sets. See the teaching in col. 8 ln. 1-10. The processing means (14) is programmed to detect the quantity of medicament dispensed compared to an intended volume of its metered dose volume (col. 8 ln. 1-3). Rocci further discloses that the pressure sensor is isolated from contact with the dispensed medicament (col. 10 ln. 23-24).

In regards to claim 34, the processing means (14) taught by Rocci is programmed to output a first signal to the display means (15) when the comparison of the quantity of medicament dispensed substantially matches intended volume (col. 8 ln. 61-63). After comparison and determination of correct dose the signal is sent to the display means (15) to reflect that a metered volume dose has been dispensed (col. 9 ln. 12-16).

In regards to claim 35, Rocci discloses that the processing means produces a second signal to the display means (15) (col. 9 ln. 10-11; Fig. 7) when the comparison is

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substantially less than an intended volume of the metered volume dose, see col. 8 ln. 64-67 & col. 9 ln. 1-7.

In regards to claim 36, the signal sent by the processing means (14) of Rocci, Jr. et al. to the display means (15) in the event of a false pulse is indicative that the proportion of the volume of the dose dispensed is less than a full dose as "the message would change to indicate the fault" (col. 9 ln. 7). This is interpreted as that the second signal contains data indicative of the proportion of the intended volume of the metered volume dose actually dispensed.

In regards to claim 37, the signal sent by the processing means (14) of Rocci, Jr. et al. to the display means (15) in the event of a false pulse changes the message "to indicate the fault" (col. 9 ln. 8) and the "dose count ... and messages would be redisplayed" (col. 9 ln. 12). This is interpreted as that the second signal is used to update the display means to reflect that a proportion of a metered volume dose has been dispensed.

In regards to claim 38, it is the examiner's position that the message of a fault pulse sent by the processing means (14) to the display means (15) taught by Rocci, Jr. et al. as well as the redisplaying of the dose count would alert the user that a full dose was not administered and to administer another dose. Thus the second signal can be used to produce an alert to instruct a user to administer a further dose.

In regards to claim 39, the dose count taught by Rocci, Jr. et al. being displayed on the display means (15) and modified by the processing means (14) and the algorithm

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of determining legitimate doses is an accumulated volume variable indicative of the medicament dispensed.

In regards to claim 40, the second signal sent by the processing means (14) to the display means (15) updates the accumulated volume variable, see col. 9 ln. 8-11. The accumulated volume variable is updated by the second signal, which is indicative of a less than substantial metered volume dose, by redisplaying the dose count to reflect a full dose was not dispensed and displaying a message indicative of the possible causes of the improper dose.

In regards to claim 41, Rocci, Jr. et al. teaches that the displayed dose count can be either incremented to display the doses used or decremented to display the doses remaining (col. 7 ln. 29) to update the display means (15) to indicate the quantity of medicament dispensed from the container.

In regards to claim 42, the microprocessor (14) taught by Rocci, Jr. et al. measures both duration, in the example of a 'clogged orifice' message being displayed when "the pulse width exceeded the ideal pulse width by approximately 50%" (col. 8 ln. 65) and amplitude, in the example of an 'almost empty' message being displayed when "peak pressure value of less than approximately 75% of the ideal pulse peak value" (col. 8 ln. 65).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**6. Claims 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rocci, Jr. et al. (6,138,669) as applied to claim 42 above, and further in view of Andersson et al. (5,331,953).**

In regards to claim 43, Rocci teaches all the limitations of claim 42 as discussed above, however is silent to applying a band-pass filter to the pressure signature recorded by the pressure sensor. Andersson et al. teaches an "inhaler intended for measuring and recording the course of inhalation of a patient" (Andersson, Abstract) which uses "a band pass filter 18" (Andersson, col. 3 ln. 66) to filter the signals for processing. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the signal processing of Rocci, Jr. et al. to include a band-pass filter as taught by Andersson et al., because applying filters in signal



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processing is a well-known step to get rid of unwanted signal components such as noise.

In regards to claim 44, the modified Rocci processing means (14) is able to select a signature envelope for further signal processing since it takes the original signal and filters with the band-pass filter and compares the filtered signature envelope "to a predetermined 'desired pulse'" (Rocci, col. 8 ln. 2).

**7. Claims 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rocci, Jr. et al. (6,138,669) as applied to claim 42 above, and further in view of Newell (5,224,484).**

In regards to claim 45, Rocci teaches all the limitations of claim 42 as discussed above, however is silent as to applying a notch filter to pressure signals during signal processing. However, Newell teaches a similar pressure signal processing method for an automatic blood pressure gauge. Newell's signal processing method "includes a notch filter, set to substantially attenuate the valve switching frequency" (Newell, col. 3 ln. 60) whose function is to eliminate any unwanted components of the pressure signal such as noise. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the signal processing of Rocci, Jr. et al. to include a notch filter as taught by Newell, because applying filters in signal processing is a well-known step to get rid of unwanted signal components such as noise. Modifying Rocci, Jr. et al.'s signal processing steps to include notch filter would yield it capable of

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manipulating the signature into segments of equal time duration or any other parameter desired.

In regards to claim 46, the modified Rocci processing means (14) is able to compare the notch filtered segments it to a predetermined 'desired pulse' data set (Rocci, col. 8 ln. 2).

**8. Claims 47 and 52-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rocci, Jr. et al. (6,138,669) as applied to claim 33 or 52 above, and further in view of Smith et al. (6,968,840).**

In regards to claim 47, Rocci teaches all the limitations of claim 33 as discussed above, however is silent as to the pressure sensor being an acoustic sensor and in turn the signature being an acoustic signature as claimed. Smith et al. teaches an aerosol generator that employs an acoustic sensor to detect various breathing characteristics during use. See col. 6 ln. 48 of Smith. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the pressure sensor of Rocci, Jr. et al. with an acoustic sensor as taught by Smith et al., because an acoustic sensor is well known in the art and it appears that Rocci's device would perform equally well with an acoustic sensor.

In regards to claim 52, the combined Rocci and Smith's device has the pressure sensor in acoustic contact with an acoustic chamber. See Smith et al. in col. 6 ln. 48-50 that the sensor that is activated through passing the respiratory flow ... through an

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acoustic chamber. The sensor being activated by flow through an acoustic chamber requires acoustic contact with the chamber as claimed.

In regards to claim 53, Rocci in Fig. 3 shows the housing having a stem block (10) with a conduit for directing medicament, an outlet (11). The modified Rocci has the acoustic chamber located in acoustic contact with the conduit. See Fig. 3 of Rocci which shows the chamber (7) in acoustic contact with the conduit (9) for activation of the sensor by the flow through the chamber (7).

In regards to claim 54, the modified inhaler of Rocci, Jr. et al. comprises "a transfer channel 7" (Rocci, col. 4 ln. 56) which is structurally a function equivalent to an acoustic chamber located within the stem block as claimed because it is capable of facilitating acoustic waves throughout its length.

In regards to claim 55, as seen in Fig. 3 of Rocci, Jr. et al., the pressure sensor (12) is located on an external surface of the stem block, or channel body (10).

In regards to claim 56, Figs. 1 and 3 of Rocci, Jr. et al. also shows that the pressure sensor (12) forms the rear wall of the functionally equivalent acoustic chamber, or transfer channel (7) of the inhaler.

**9. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rocci, Jr. et al. (6,138,669) as applied to claim 33 above, and further in view of Wachter et al. (5,794,612).**

In regards to claim 48, Rocci has everything as claimed but does not explicitly teach the exact type of pressure sensor used. Wachter et al. teaches an MDI device

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which uses a pressure sensor which is a "strain-gage based device" (Wachter, col. 3 ln. 65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the pressure sensor of Rocci, Jr. et al. with the strain-gage based sensor as taught by Wachter et al., because this type of strain-gage based pressure sensor is well known in the art and it appears that Rocci's device would perform equally well with an acoustic sensor.

**10. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rocci, Jr. et al. (6,138,669) and Smith et al. (6,968,840) as applied to claim 47 above, and further in view of Marnfeldt et al. (5,839,429).**

In regards to claim 49, the modified Rocci's reference has everything as claimed but is silent as to the acoustic sensor being a microphone as claimed. Marnfeldt et al. teaches an inhaler "connected to a processing device ... for detecting when the inhaler is activated" (Marnfeldt, Abstract) which includes a "microphone 16" (Marnfeldt, col. 2 ln. 14) that detects "the sound of the airflow at an inhalation" (Marnfeldt, col. 2 ln. 20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the acoustic sensor of the modified Rocci's device with the microphone as taught by Marnfeldt et al., because Marnfeldt et al. states that the microphone detects the "activation of the inhaler" (Marnfeldt, col. 2 ln. 10) and works toward "training a patient to use an inhaler correctly" (Marnfeldt, col. 1 ln. 30).

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**11. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rocci, Jr. et al. (6,138,669), Smith et al. (6,968,840), and Marnfeldt et al. (5,839,429) collectively as applied to claim 49 above, and further in view of Haronian et al. (5,856,722).**

In regards to claim 50, the modified Rocci's reference has everything as claimed but is silent to the microphone being a micro-electro-magnetic microphone as claimed. Haronian et al. teaches an "improved microelectromechanical (MEM) acoustomechanical structure capable of sensing vibratory motion, and particularly acoustical vibrations" (Haronian, col. 3 ln. 61). This MEM structure taught by Haronian et al. is a microphone per its ordinary definition: 'an instrument that converts sound waves into electric current'. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the modified Rocci's microphone with the MEM microphone as taught by Haronian et al., because Haronian et al. states that the MEM microphone is "integrated into a single crystal silicon substrate with electrical circuitry for performing acoustic signal processing functions" (Haronian, col. 4 ln. 5).

**12. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rocci, Jr. et al. (6,138,669) and Smith et al. (7,331,339) as applied to claim 47 above, and further in view of Ivri et al. (6,205,999).**

In regards to claim 51, the modified Rocci's reference has everything as claimed but is silent as to the acoustic sensor being comprised of piezoelectric material. Ivri et al. teaches a similar portable inhaler with an inhalation flow sensor "constructed from a

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piezoelectric film component" (Ivri, col. 8 ln. 23). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Rocci's acoustic sensor to be made out of piezoelectric material as taught by Ivri et al., because Ivri et al. states that "the piezoelectric film component produces an electrical signal when it deflects" (Ivri, col. 8 ln. 24).

**13. Claims 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rocci, Jr. et al. (6,138,669) as applied to claim 33 above, and further in view of Nöhl et al. (6,390,088).**

In regards to claim 57, Rocci has everything as claimed but is silent as to comprising a pyroelectric sensor. Nöhl teaches an aerosol inhaler comprising multiple "thermal sensor[s] 5" (Nöhl, col. 6 ln. 5) which detect the fall in temperature caused by dispensation of the medicament. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Rocci's pressure sensor with thermal sensors as taught by Nöhl et al., because Nöhl et al. states that "the signal from the first thermal sensor ... permits the emitted quantity of aerosol to be deduced" (Nöhl, col. 2 ln. 46).

In regards to claim 58, the modified Rocci's device with the thermal sensor of Nöhl "generates a reference signal which is likewise fed to the evaluating electronic unit" (Nöhl, col. 2 ln. 43) which is the processing means for Nöhl. The thermal sensor being applied to Rocci, Jr. et al. would in turn be connected with Rocci's processing

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means (14) and would function to relay signals indicative of the temperature to the processing means (14) for comparison against control sets.

In regards to claim 59, Rocci and Nöhl teach processing means that compare received signals against control sets. Nöhl et al. teaches that "prior to the atomization the environmental temperature of the thermal sensor, ... can be detected, digitalized and stored in the evaluating electronic unit" (Nöhl, col. 2 ln. 65-67 & col. 3 ln. 1) and the processing means (14) of Rocci is "programmed to compare the measured pressure pulse and compare it to a predetermined 'desired pulse'" (Rocci, col. 8 ln. 1) as claimed.

### ***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following patents are considered to be pertinent art: Jones et al. (2003/0075171), Lloyd et al. (5,469,750), and McKinnon et al. (6,190,326) are cited to show different inhalers comprising sensors and processing means.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLIN STUART/  
Examiner, Art Unit 4177

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771